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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/664,490	09/17/2003	John F. Boylan	ACS 65471 (2133XXD)	4845

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EXAMINER
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MENDOZA, MICHAEL G

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 09/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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**Office Action Summary**

Application No.

10/664,490

Applicant(s)

BOYLAN ET AL.

Examiner

Michael G. Mendoza

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 June 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-5 and 32-43 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-5 is/are allowed.
- 6) ☒ Claim(s) 32-43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Response to Arguments***

1. Applicant's arguments, see page 8, filed 27 June 2005, with respect to 1-5 have been fully considered and are persuasive. The 35 USC 112 rejection of claims 1-5 have been withdrawn.
2. Applicant's arguments, see page 9, filed 27 June 2005, with respect to the rejection(s) of claim(s) 32-37 under 35 USC 102(e) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Daniel et al. The Applicant has amended the claims and argues that Daniel et al. does not teach a layer of polymeric material. Daniel et al. teaches the use of a heparin coating as an antithrombotic material. As stated in the previous office action PTFE (TEFLON) and polyimide are well known alternatives for preventing clotting. Therefore, it would be obvious to use PTFE (TEFLON) or polyimide as an alternative for preventing clots.
3. The Applicant also argues that Daniel et al. fails to teach wherein the layer is deposited on regions which experience low strain. Claim 36 uses the claim terminology "comprising" which makes the claim an open ended claim. Since the claim is an open ended claim the limitation "a layer of polymeric material deposited on the regions which experience low strain" does not exclude the rest of the regions of device. Daniel et al. teaches that all of the device is coated, which includes any region of low strain.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 38-40 and 43 are rejected under 35 U.S.C. 102(e) as being anticipated by Daniel et al. 6663652.

6. Daniel et al. teaches an embolic protection device for capturing embolic debris released into the body vessel of a patient, comprising: a shaft member having a distal end and a proximal end; a filtering element mounted on the shaft member near the distal end thereof, the filtering element including an expandable strut assembly and a filter attached to the strut assembly for capturing embolic debris (fig. 15), and a coating made from a substance having a coefficient of friction less than the coefficient of friction of the material forming the strut assembly selectively deposited on portions of the strut assembly proximal to the filter; wherein the coating substance is a hydrophilic substance; wherein the coating substance is heparin (col. 19, lines 1-5); and wherein the expandable strut assembly is made from a material having self-expanding properties (col. 3, lines 26-29).

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 32-37, 41, and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daniel et al. 6663652 in view of Chin et al. 5928260.

9. Daniel et al. teaches an embolic protection device for capturing embolic debris released into the body vessel of a patient, comprising: a shaft member having a distal end and a proximal end; and a filtering element mounted on the shaft member near the distal end thereof, the filtering element including an expandable strut assembly and a filter attached to the strut assembly for capturing embolic debris. It should be note that Daniel et al. fails to teach a layer of polymeric material having a coefficient of less than the coefficient of friction of the material of the strut assembly deposited on at least part of the strut assembly proximal to the filter. Daniel et al. teaches an antithrombotic material applied to the device.

10. Chin et al. teaches a device with a common coating of heparin for preventing clotting (col. 6, line 3-9). Chin et al. also teaches that polymers having the same properties as heparin for preventing clotting can be used as alternative to heparin. One alternative taught is TEFLON (PTFE). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use PTFE or polyimide as an obvious alternative to using heparin because of the similar

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characteristic of preventing clotting on materials that they are applied to (col. 6, lines 3-9).

***Allowable Subject Matter***

11. Claims 1-5 are allowable over the prior art of record.
12. The following is a statement of reasons for the indication of allowable subject matter: the prior art of record fails to teach or render obvious the overall claimed invention of an embolic protection device for capturing embolic debris released into a body vessel of a patient, comprising: a filtering assembly being mounted on an outer tubular member which is coaxially disposed over an inner tubular member having a length shorter than the outer tubular member, wherein one end of the inner tubular member is adapted to abut against a stop fitting located on a shaft member for limiting axial movement of the filter assembly along the shaft member.

***Conclusion***

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

### **Contacts**


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Mendoza whose telephone number is (571) 272-4698. The examiner can normally be reached on Mon.-Fri. 8:00 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on (571) 272-44963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



MM



GLENN K. DAWSON  
PRIMARY EXAMINER